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SEMANTIC, PEDANTIC OR PARADIGM SHIFT? RECRUITMENT, RETENTION AND PROPERTY IN MODERN POPULATION BIOBANKING

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Abstract: Evolving uses of human biological material, including their collection and retention in biobanks and their distribution to diverse projects, are sites of great tension from the human rights perspective. In the medical-legal setting, these rights are often protected and realised through consent practices. In the biobank setting, there endures a widely shared concern over consent, and the many divergent ways it is fashioned and deployed. This article reconsiders consent in the biobank setting, first, addressing the theoretical foundation of consent and its deployment in the broader medical context, second, examining the nature of biobanks and the uncomfortable position of consent therein, and finally, offering a means of approaching recruitment and retention in the biobank setting which is sensitive to originator interests, including human dignity, doing so within the rubric of a property model.

Keywords: Population Biobank – Human Tissue – Consent – Withdrawal – Property – Interests

INTRODUCTION

Evolving medical and research practices, including the collection and retention of human biological material in biobanks for distribution to researchers of diverse background and interest, are considered to be of significant scientific, healthcare and commercial value,¹ but they are also sites of great tension from the human rights perspective, implicating rights to bodily integrity, self-governance, personal security, public interest and common good. In the medical setting, many of these rights are protected and realised at least in part through consent practices (as well as privacy and information security practices). Indeed stakeholders have worked terribly hard – in a setting characterised by a long history of medical paternalism and recent revelations of research abuses – to empower patients and human research subjects, and to transform their interaction with the medical-research community into a relationship of mutual trust and dialogue which operates on a morally-grounded conception of consent (ie: consent which unfolds as a process). These were achievements fought for under the banner of human dignity, and they remain incomplete and ongoing.

But biobanking is a medical endeavour of a different character and magnitude.

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¹ J. Kaiser, "Population Databases Boom: From Iceland to the US" (2002) 298 Science 1158-1161.

It sits uncomfortably at the “common good” and “individual interest” intersection, as evidenced by the pools of ink spilled, and numerous concerns aired, over its practice, and the construction and deployment of consent in the biobank setting, which is diverse and inconsistent.² Indeed, consent practices represented a central issue in the recent Tiss:EU conference,³ the inaugural output of a European FP7 project intended to assess the impact of European Union regulatory activities on member states with respect to the procurement, storage and transfer of human tissue and cells in Europe.⁴ My own concern derives from the (sometimes) unreflective use of consent in combination with its uneasy interaction with the needs and aims of the biobank setting.

Given the above, this short article reconsiders this setting, and suggests a way forward that eschews the consent paradigm, places greater emphasis on the common good elements of biobanking, and might permit us to avoid the knots in which we tie ourselves trying to make consent work in this unique and critical field of health research. First, it briefly considers the theoretical foundation of consent and its deployment in the clinical and clinical trials contexts, where its continued strength and robustness is essential (because it actually has a chance of addressing the risks to which individuals are exposed). Second, it briefly considers the *sui generis* nature of biobanks and why consent is such a vexing issue therein. Finally, it offers an alternate means of approaching recruitment and retention of participants in the biobank setting, suggesting a governance framework which is both more intellectually honest (than many current practices) and still protective of human dignity, which is such an important value in this field.⁵

I. THE MEDICAL CONTEXT: THE WHY, WHO, WHEN AND HOW OF CONSENT

There exists – particularly in the West – a strong moral conviction, grounded on notions of human dignity and respect for individual autonomy, that everyone has the right to self-determination with respect to their body. And this conviction has been translated into a legal recognition that every person has the right to have his or her bodily integrity protected against invasion by others, and the legal rule that consent must precede any such touching. Non-consensual touching, no matter how innocuous, constitutes an actionable assault, even if committed by well-intentioned medical personnel in the healthcare setting.⁶ Indeed, this protection of personal integrity, both physical and psychological, has been elevated to an international human right.⁷

Of course, the exercise of individual autonomy through the giving or refusal of consent must, in the general course, be coincident with legal competence, and the

² See G. Helgesson *et al.*, “Ethical Framework for Previously Collected Biobank Samples” (2007) 25 *Nature Biotechnology* 973-976, and others, including note 3, *infra*.

³ “First International Conference of Tiss:EU Project: Ethical & Legal Aspects of Research with Human Tissue in Europe”, 26-28 June 2008, Göttingen.

⁴ For more on the Tiss:EU Project, see <http://www.tisseu.uni-hannover.de/index.php>.

⁵ I concede that some of the argument may be seen to rest on semantics (ie: the characterisation and naming of what is transpiring at the recruitment/retention phase), but it is ultimately important for our broad understanding of the term “consent” and its retention of power, and for the theoretical basis on which we construct our involvement in biobanks more generally.

⁶ K. Mason & G. Laurie, *Mason & McCall Smith’s Law and Medical Ethics*, 7th ed (Oxford: OUP, 2006) at 349.

⁷ See *YF v. Turkey* (2004) 39 EHRR 34 (ECHR).

disclosure of information to the subject. With respect to the former – competence – it is accepted that consent is only possible within the context of relationships between people “in the maturity of their faculties”.⁸ With respect to the latter – information – it is accepted that, from a moral point of view, a person should only be exposed to risks that s/he has or can agree to;⁹ although the amount and quality of the information appropriately disclosed is much debated,¹⁰ it is generally accepted that it must be sufficient (for the reasonable person in the particular circumstances prevailing).

In the clinical setting, then, and barring the emergency situation, the patient must give his/her explicit or implicit consent prior to any medical intervention. That consent must be underwritten by legal competence to make a decision, and by sufficient disclosure of information relevant to the course recommended (which would include information about risks, benefits and potential alternatives). Although the research setting is of a different character, consent is still (viewed as) the “lynchpin” to ethical acceptability,¹¹ and consent must similarly be accompanied by competence and information disclosure. More specifically, the research subject must consent, typically in writing, prior to formally entering the research protocol. As part of that consent process, s/he must usually be advised of the nature and objectives of the particular project to which s/he is attached, and s/he must be advised of the reasonably anticipated risks, consequences and (hoped for) benefits, and the alternatives to participation.¹² Of course, all of this is done to ensure that subjects, who are often drawn from vulnerable groups, are not harmed, exposed to unnecessary risks, or unduly instrumentalised.

II. THE BIOBANK CONTEXT: AN UNEASY ACQUAINTANCE WITH CONSENT

What may not be obvious from the above articulation of consent is that there are a host of research models, each varying in the level to which the researcher interacts with or acts upon the subject. For example, research relying on material contained in biobanks is of a different hue than clinical trials relying on the active involvement of individual participants (and there are a variety of different types of biobanks), and research on data alone is of a further differing character. For present purposes, let us

⁸ J. Mill, “On Liberty” in M. Warnock (ed.), *Utilitarianism, On Liberty and Other Essays* (London: Fontana, 1962), at 135. Competence exists when the individual has the ability to: (1) understand and recall information relevant to the medical course under consideration; (2) process or deliberate on that information; (3) decide to accept or reject a particular course, having weighed the nature, risks and consequences of a course as well as the alternatives; and (4) communicate that decision. Special rules and procedures exist with respect to minors and the mentally incapacitated.

⁹ K. Mason & G. Laurie, *supra*, note 6, at 395-399.

¹⁰ One might note here O. O’Neill, “Some Limits of Informed Consent” (2003) 29 JME 4-7, who is sceptical about how much we demand of consent, questions the extent to which it truly empowers people, and suggests that its value is really limited to ensuring that people are not deceived.

¹¹ K. Mason & G. Laurie, *supra*, note 6, at 655.

¹² For more on the demands of consent in the research setting, see the Medical Research Council’s *Good Research Practice* (2000) and *Human Tissue and Biological Samples for Use in Research – Operational and Ethical Guidelines* (2001/2005), the European Union’s Directive 2001/20/EC and Directive 2005/28/EC, both of which lay down good practice for clinical trials on medicinal products for human use, the European Council’s Convention on Biomedicine (1997), the World Medical Association’s Helsinki Declaration (2000), the Council for International Organizations of Medical Sciences’ Guidelines on Human Subject Research in Developing Countries (2002), and the Council of Europe’s Additional Protocol on Human Subject Research (2005).

focus on research on tissues or generated data (genetic, phenotypic, lifestyle, environmental, and demographic) held in new biobanks, of which there was a boom in formation with the turn of the millennium.¹³ In contradistinction to old and sometimes surreptitiously accumulated collections of biological samples – which raise their own special concerns – modern biobanks are unique in that they are:¹⁴

- collective – they rely on mass participation;
- inclusive – they often recruit healthy people and are often deemed most effective when they also include children recruits;
- prospective – they endure for a long time into the future and ideally beyond the life of original participants; and
- purposively indeterminate – it is impossible to inform participants of specific future research ends and therefore of potential risks and benefits.

As a repository of samples and data intended for future, ongoing and repeated use, we do not (and cannot at the time of tissue collection) know:

- the identity or location of all the potential users;
- the ends to which all the research will be put;
- the eventual (but hopefully therapeutic) outputs;
- the governance structures of the place(s) where materials will be used;
- the lifespan or security of the biobank.

In short, biobanks are an exercise in the unknown; they are future-oriented and optimistic; although we believe they will contribute to high-powered future research, new understandings, and the discovery and generation of new therapeutic products and processes, we really do not know what their ultimate value or their social risks/consequences might be.

This veiled future, together with past scandals and missteps,¹⁵ has been the source of much consternation, and has spawned a groundswell of governance activity, some of it binding regulation, much of it not.¹⁶ Unfortunately, much of this

¹³ B. Elger & A. Caplan, “Consent and Anonymization in Research Involving Biobanks” (2006) 7 EMBO Reports 661-666.

¹⁴ For more on their nature, see G. Williams, “Bioethics and Large-Scale Biobanking: Individualistic Ethics and Collective Projects” (2005) 1 GSP 50-66.

¹⁵ With respect to practices concerning previously existing biobanks, one might note the Alder Hey and Bristol scandals in the UK. With respect to missteps regarding prospective biobanks, one might note the Icelandic Health Sector Database.

¹⁶ Note that Australia, Canada, Estonia, France, Germany, Iceland, Japan, Sweden, Switzerland, the UK and the USA have all issued their own guidelines, and see the WMA’s Declaration on Ethical Considerations Regarding Health Databases (2002), UNESCO’s International Declaration on Human Genetic Data (2003), the COE’s draft Recommendation on Research on Biological Materials of Human Origin (2006), and the OECD’s draft Guidelines for Human Biobanks and Genetic Research Databases (2008).

regulation is inconsistent, even on the all-important issue of consent,¹⁷ where, in addition to minor variations in terms and practices that are discernable from country to country, there exists a more fundamental divergence in approach as between North America and Europe.¹⁸ In the former, many biobanks have tried to employ a limited or specific consent, which has led to a reliance on a multi-layered approach and a long, detailed form by which the individual agrees to specified uses.¹⁹ Contrarily, in much of Europe and elsewhere, the very concept of consent has been stretched to include a “blanket consent”, “broad consent”, “comprehensive consent”, or “general consent”, where originators are asked to consent to their material (physical and informational) being used in unspecified future research. In such a situation, the “informedness” which underlies proper, ethical consent cannot be fulfilled, making any claim to having obtained consent as we wish and need it to mean in the clinical and research setting a fallacy. As a concession to the impossibility of respecting people through robust consent,²⁰ participants are not infrequently given a right to withdraw from the biobank at any future time without the need to give reasons and without fear of adverse consequences.

Given the demands of consent in the clinical and clinical trials setting, the nature of biobanks, and the uncertainties and inefficiencies created by diverging approaches, why are we still talking about “consent” in the biobank setting? The very use of the term raises as many questions as it assuages concerns. For example, consent-related issues that remain the subject of debate (and which were raised to varying degrees at the recent Tiss:EU conference) include:

- whether the consent obtained (particularly under past practices) relates to use of the tissue, or use of the data, or both;
- whether ethical consent properly demands the re-contacting of tissue originators for each new use not specifically consented to in the original exercise;²¹ and
- whether consent, particularly re-contacting, introduces notions of ownership of excised body parts and generated data and injects notions of property over the

¹⁷ B. Knoppers, “Biobanking: International Norms” (2005) 33 J Law Med Ethics 7-14.

¹⁸ B. Elger & A. Caplan, *supra*, note 13. However, note might be taken of the efforts of P3G to produce a generic consent form so as reduce inconsistency and inefficiency: B. Knoppers, “Biobanking, Population Genetic Research and Informed Consent”, presented at “One Origin, One Race, One Earth: Genetics, Human Rights and the Next Phase of Human Evolution”, U. of Calgary, 16 November 2007, Calgary, Canada.

¹⁹ The USA has wedded this to an expansion of the definition of “non-identifiable”; information so characterised is seen as carrying no risk to the originator and so relieves the researcher of the burden of re-contacting.

²⁰ A “robust consent”, in my view, is an ongoing, information-reliant exchange between parties, and this cannot effectively and efficiently be realised in the biobank setting. Having said that, I concede that some might defend this broad consent as perfectly justifiable (or robust) on the basis that research activities with which the biobank is associated will be made public and people who bother to keep themselves informed often have the right to withdraw their consent, thereby preserving consent as a process.

²¹ An approach which recognises consent as a process rather than an event, but which has been challenged as prohibitively expensive, inefficient and potentially impossible: P. Furness & M. Nicholson, “Obtaining Explicit Consent for the Use of Archival Tissue Samples: Practical Issues” (2004) 30 JME 561-564.

body.²²

Despite these resolution-resistant issues, we seem to have an irresistible inclination to force many (or most) medical ethical issues into the consent paradigm, an inclination which has already been challenged by commentators noting that consent is not the only answer to all ethical concerns,²³ but is rather simply a means to an end, that end being to respect persons and their interests.²⁴

Certainly we can perform a comprehensible and robust consent process with respect to the physical act of excising the tissue itself, and this seems rather unproblematic. However, for most other treatments of the tissue and its generated data, and its use by (unknown) future researchers, we should be very reluctant to call what we are doing “consenting the subject” as that important term and essential practice is manifested in other medical settings. We must recognise that the consent paradigm is ill-fitting to the biobank setting with the result that, with respect to the overall undertaking, we can only ever achieve a shadow of consent, particularly in new, broad-purpose, future-oriented biobanks such as UK Biobank and Generation Scotland.

III. BIOBANK GOVERNANCE: A FRAMEWORK FOR MOVING FORWARD (AND MOVING ON)

Rather than continue the intellectual and practical struggle (and wheel-spinning) over how to make consent work in the biobank setting, we might just look for an alternative model; one that (1) respects the originator, (2) promotes his/her trust in the endeavour, and (3) assures the stability of the biobank’s resources, while simultaneously preserving our association of consent in the medical context with something relational, powerful and directed at a specific matter. I suggest that this might be done by extending the property model which already suffuses the human tissue realm.

Although the current general position is that there can be no property in the human body,²⁵ this is not a consistently applied proposition. For example, with very little additional contribution,²⁶ third parties can obtain property in corpses, biological products of the body, and excised body parts and tissues.²⁷ In short, property rights are already enforced at various stages of our treatment with the body, and property concepts pervade the law governing the human body – even to the point of characterising the transfer of tissue from originators to third parties as “donation”,

²² A notion which has been strenuously resisted by many stakeholders who are concerned with commodification of the (whole) human body and with tissue originators deriving any financial benefit therefrom.

²³ O. Corrigan, “Empty Ethics: The Problem with Informed Consent” (2003) 25 *Sociology of Health & Illness* 768-792.

²⁴ K. Mason & G. Laurie, *supra*, note 6, at 682.

²⁵ A proposition which finds its origins with Coke (see P. Skegg, “Human Corpses, Medical Specimens and the Law of Property” (1975) 4 *Anglo-Am Law Rev* 412) and which has been reiterated in judicial precedents and policy statements, including the Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (London: Nuffield Council, 1995), and the UK *Human Tissue Act 2004*.

²⁶ And under exceptions that have been characterised as misguided and insufficient: see R. Hardcastle, *Law and the Human Body: Property Rights, Ownership and Control* (Oxford: Hart Publishing, 2007), at 143.

²⁷ See the discussion in S. Harmon, “A Penny For Your Thoughts, A Pound For Your Flesh: Implications of Recognizing Property in Human Body Parts” (2006) 7 *Med Law Int* 329-354.

which assumes some proprietary interest – but property rights are generally denied to originators.²⁸ However, to recognise originator property interests would require only a minor adjustment in our theoretical thinking, and such becomes more palatable if the nature of property is understood.

Properly understood, the recognition of property in something is the recognition of a relationship of interest to that subject in a person.²⁹ Property rights are a variable and shifting bundle of rights and duties which attach to definable, identifiable, transferable subject matters or items,³⁰ and the long-established right to control our (whole) bodies and to enjoy bodily integrity and be free from invasion is consonant with this construction.³¹ Moreover, property is not a natural right, it is merely a socially-constructed right which is legally defined and has evolved over time; it is a social institution which organises items (and services) for which there is greater demand than supply.³² Moreover, it has certain attributes which make it amenable to absorbing originator claims in this setting, including the following:

- Versatility: The property model has metamorphosised over the centuries as a result of changing concepts of social and economic value, addressing realty, chattels, intellectual products, personality and image, and other areas of human endeavour over which we wish to exercise personal control.³³
- Limitability: It recognizes moral limitations in the use of objects over which we have rights and vindicates them through legal limits.³⁴
- Sensitivity: It is sensitive to, and interacts with, other areas of law, cooperating with public and private domestic and international law (eg: unfettered enjoyment of property is restricted by traffic, planning, conservation, environmental, and other public laws).³⁵

By extending the property model to originators, we recognise that they have interests and deserve rights of control as against others, and that, within legally defined limits, they can alter or transfer their rights by agreement. The following sections consider recruitment and retention in the biobank setting within the rubric of a property model, the idea being to fashion a system that respects the originator, promotes his/her trust in the endeavour, and assures the stability of the biobank's resources while preserving

²⁸ An outcome recognised by Broussard J, dissenting, in *Moore v. Regents of the University of California* (1990), 793 P 2d 479 (Cal SC), reversing (1988), 249 Cal R 494 (CA).

²⁹ P. Matthews, "Whose Body? People As Property" (1982) 36 Current Legal Problems 193-239, and K. Gray, *Elements of Land Law* (London: Butterworths, 1987), at 8.

³⁰ P. Matthews, *ibid*, at 193-195, J. Weisman, "Organs As Assets" (1993) 27 Israel LR 610-623, at 610, R. Smith, *Property Law*, 3rd ed. (London: Longman, 2000), at 3, and others. And see recent judicial statements to this effect in *Phillips v. Washington Legal Foundation* (1998), 524 US 156 (SC) and *Yanner v. Eaton*, [1999] HCA 53 (HCA).

³¹ In the UK, this was enunciated in W. Blackstone, *Commentaries on the Laws of England*, 1783, 9th ed., vol I, at 129, and recently reiterated in the medical context in *Re F (Mental patient: Sterilisation)*, [1990] 2 AC 1 (HL) and *Chester v. Afshar*, [2005] 1 AC 134 (HL).

³² J. Harris, "Who Owns My Body?" (1996) 16 Oxford J Law Soc 55-84, at 56-57.

³³ P. Matthews, *supra*, note 29, at 252-255, and K. Gray, *Elements of Land Law* (London: Butterworths, 1987), at 11, where it is noted that the changing objects of property has resulted in the abandonment of property in wives and slaves.

³⁴ J. Harris, *supra*, note 32, at 60-61, and S. Worthington, *Personal Property Law* (Oxford: Hart Publishing, 2000).

³⁵ S. Worthington, *ibid*, at 3.

our understanding (and ideal) of consent as outlined above.³⁶

(1) Recruitment: Obtaining Originator Material

Currently, and without enumerating all of the many ways in which (potential) originators may be identified and contacted, recruitment is achieved through the solicitation of consent to participate. In the European context, the consent sought is broad and general and suffers from the frailties noted above. However, it is perhaps more desirable to separate the excision and the use of the tissue into separate processes.

With respect to the first process – excision – we can sensibly imagine (and perform) a robust consent process as it is idealised and understood in the clinical setting. The originator and exciser, who may have an ongoing clinical relationship, meet in a place where an exchange of information about the procedure, its risks, and its consequences can be fully realised. The originator can probe, ask questions, or articulate fears, and the exciser can respond, assuage, and proceed (or not), and s/he can follow up in the usual post-procedure manner to ensure full recovery from the intervention. Ultimately, the originator consents to an excision of tissue for the purpose of offering that tissue to a biobank. As suggested above, this preserves our (hard fought for) understanding of consent and seems largely unproblematic.

It is with the second process – subsequent (often unspecified) use of the tissue and generated data – that consent encounters its insurmountable hurdles. Here we might be better served recognising that people have property in their bodies, including their excised tissue and generated data.³⁷ So doing respects people by taking notice that they have interests in relation to both their whole, undivided selves and their divided or separated selves (a condition which is increasingly important in the modern biotechnological context).³⁸ The objective, then, is to fashion an event under this model which, in the context of recruiting participants, recognises and addresses these interests, which interests I contend are as follows:³⁹

(1) an interest in influencing the use and disposal of excised tissue;

³⁶ I recognise that the extension of the property model to originators would necessitate rationalisation of both the property and human tissue use regimes. Exploring the contours of that rationalisation is beyond the scope of this modest work. I also recognise that the tide is running against the recognition of property at present, though the effect of such a recognition might be that practices around human tissue use might become more principled: see R. Hardcastle, *supra*, note 26, at 172.

³⁷ I recognise that a widely shared concern with the adoption of a property model is that a market may emerge around the sourcing of body materials from originators. Addressing this concern is beyond the scope of this short article, but I note several points: (1) property is not inseparable from markets; (2) individuals can have property rights in something without the concomitant right to divest themselves of that item for money; (3) resistance to a property model has done nothing to avoid the formation of (black) markets in body material.

³⁸ One can assume that a person who loses a finger in an accident would claim a right to possess and control (a property interest in) that excised part despite its separation, and there would be few so bold as to deny that interest, but there is little in the way of legal protection of that interest.

³⁹ Hardcastle, *supra*, note 26, at 1 and 173, articulates four of these interest. With respect to the first two interests, however, he suggests that they are interests of control – control of the disposal and profits. However, I believe we need to recognise that we do not live as islands unto ourselves (to borrow a phrase from J. Donne, Meditation XVII, “Devotions Upon Emergent Occasions” (1624), at http://en.wikipedia.org/wiki/john_donne [accessed 24 Aug 2005]). As such, we should recognise that full and individual “control” may rarely ever be possible (or appropriate); there are many things, both important and intimate, that we do not “control”. Though “control” may be the deep-seated desire, I think the defensible interest is rather one of “influence”.

- (2) an interest in influencing the profits that may be derived from the tissue;
- (3) an interest in being free from emotional distress;
- (4) an interest in preserving his/her autonomy; and
- (5) an interest in contributing to knowledge for the improvement of human well-being and health.⁴⁰

An event which recognises and addresses these interests, without necessarily vindicating all of them, together with the framework which supports that event, is the means through which we extend respect to originators of material in the biobank setting.

Let us turn first to the framework, which ought to be strong, transparent, consistent for biobanks within a jurisdiction, and, ideally, replicated in large part across jurisdictions. The UK Biobank's governance regime represents a valuable existing model,⁴¹ but it is, of course, neither statutorily set nor binding on other biobanks with which UK Biobank might interact. The Council of Europe's Recommendation on Research on Biological Materials of Human Origin (2006),⁴² represents a commendable first effort at offering a harmonised model, but, as I note elsewhere,⁴³ it falls well short of an ideal (and, in any event, relies squarely on the consent paradigm). Given the needs identified, a statutory framework would be best. Preliminarily, one expects that the necessary governing framework would have to:

- identify and define governing values (eg: solidarity, human dignity, autonomy, equality, trust, etc.);
- articulate biobank objectives/duties, including the use of its resources to contribute to basic knowledge, public health, saving lives, and improving life-quality;
- enunciate ethical guidelines re: best research practice (to be applied to all research projects submitting a request to the biobank for material), together with a concise statement of the types of research for which the biobank's resources will never be used;
- erect security protocols and practices for protecting the privacy of originators,

⁴⁰ This interest is grounded on solidarity, a moral value we all share to varying degrees and one that underscores our shared objectives (and indeed duties) toward contributing to the welfare of our shared communities and our fellow man. This value has been explored in greater detail by S. Harmon, "Solidarity: A (New) Ethic for Global Health Policy" (2006) 14 Health Care Analysis 215-236.

⁴¹ See UK Biobank, Ethics and Governance Framework, v. 3, 2007, at <http://www.ukbiobank.ac.uk/docs/EGF20082.pdf> [accessed 17 July 2008].

⁴² Rec(2006)4, March 15, 2006, 958th Meeting of the Ministers' Deputies.

⁴³ S. Harmon, "The Recommendation on Research on Biological Materials of Human Origin: Another Brick in the Wall" (2006) 13(3) European J Health Law 293-310. For a further examination of the final version of the Recommendation, see H. Nys, "Research on Human Biological Materials and the Council of Europe: Some Unanswered Questions, Overlaps and Empty Boxes" (2008) 15 European J Health Law 1-6.

relying on terms that are harmonised across jurisdictions;

- enumerate the duties of the custodian of the biobank, including explicit duties to proactively and demonstrably steer the usage of the biobank toward broadly beneficial projects that will enhance (public) healthcare and thereby maximise their contribution to worthy, publicly-endorsed ends;⁴⁴
- outline the decision-making processes to which the custodian must adhere, as well as the custodian's monitoring duties, together with instructions as to when the custodian should exercise the right to withdraw the biobank's resources from a project;
- require that all research entities submitting a request to the biobank for material (1) meet the biobank's guidelines for best practice, (2) receive permission from an external, independent ethical review board, and (3) verify that they understand their duties with respect to dissemination of knowledge and benefits derived from their use of the resource;⁴⁵
- require an ethical governance committee comprised of ethical, policy, legal, lay and scientific members to whom the custodian reports regularly, and which conducts regular audits on implementation of procedures;
- make the biobank sensitive to public opinion by erecting a public engagement process with components that are both (1) general and ongoing, and (2) limited, focused and initiated from time to time, thereby promoting public input, particularly with respect to technological changes or new understandings that might shift research agendas;
- address the economics of running a biobank, including funding sources and allowable fees for making the resource available to private researchers;
- enumerate prohibited actions in relation to the custodian and the users (researchers);
- enumerate sanctions for breaches of its provisions, enforceable against the custodian and against users (researchers) by the statutory oversight body;
- address the very real possibility of collapse and cessation of activities, articulating baseline principled rules with respect to winding down and the transfer or destruction of the material which made the resource so valuable in the first place.

This framework should recognise the originator's proprietary interests in his/her

⁴⁴ A duty suggested by G. Williams & D. Schroeder, "Human Genetic Banking: Altruism, Benefit and Consent" (2004) 23 New. Gen & Soc. 89-103, at 97.

⁴⁵ It is important to erect duties for private, profit-seeking research entities because biobank usage is now, and is expected in future, to be driven largely by economic interests, and because publics have concerns around the role and conduct of profit-seeking entities in human subject research and public healthcare agenda-setting: G. Williams, *supra*, note 14, S. Wilkinson, "Biomedical Research and the Commercial Exploitation of Human Tissue" (2005) 1 GSP 27-40, and others.

excised tissue and generated data, and should elucidate of the full scope of concomitant rights an originator can exercise with respect to excised tissue and its generated data. The originator is respected at the outset insofar as his/her interests are given voice. Where an interest is not vindicated, respect is still extended insofar as principled reasons for the failure would be articulated. In this way, the originator is made to understand what portion of the bundle of rights that is his/her property interests is transferred to the custodian, and what additional rights and duties the custodian has in that item to which property attaches (ie: in the tissue and data).⁴⁶

With respect to the mechanics of the event, the competent originator (or his/her guardian/proxy) would be provided with all of the information associated with the framework and its operation, and the exercise of rights necessitated by it (and by whom). The originator would then “agree” to “transfer control” over the material to the custodian of the biobank. By this transactional event, the originator’s relationship with (and claim to) the material is ultimately severed and, to use a property term, s/he abandons his/her claim to the material, agreeing that it is the custodian who thereafter constitutes the only individual who can give “consent” to the use of the material for specific projects. However, the originator does so on the understanding that clear parameters for the use of the material by the biobank and others exist, and certain ethical thresholds will be enforced in the later use of that material.

Returning to the originator’s interests, by choosing to participate in an endeavour with the above framework, which addresses future use broadly, penalties for failures, and disposition when (if) winding up the biobank, the originator has made a decision which might be characterised as “influencing” the use and disposal of excised tissue. Similarly, although s/he does not have a direct and immediate influence over the profits generated by the biobank or the client researchers, the careful selection by the custodian (as directed by the framework) of the most publicly appropriate projects (which might contain benefit sharing elements) goes some way in addressing this interest. No one can be guaranteed freedom from emotional distress (and some become more easily distressed than others), but the framework outlined, which includes specific “no-go” areas, monitoring, and provisions for prosecution of breaches should give the originator some solace that all of the research supported will be such that s/he need not become distressed. The originator’s autonomy is fully respected through the dualistic recruitment process, and is thereafter not implicated by the use of the material (so long as informational security is enforced, and same is clearly addressed by the framework). Finally, the originator is obviously assured that s/he is contributing to knowledge for the improvement of human well-being.

Importantly, the biobank is not getting the consent of the originator to use the material in future research. Rather, it is obtaining all of the property interests in the material from the originator so that the biobank (or its custodian) can exercise consent with respect to all individual research projects as they are proposed. This process takes place within a strong framework by which the originator is assured that s/he can trust in the undertaking (and in science, its tools and its protagonists more generally).⁴⁷

⁴⁶ I recognise that one cannot convey more interests or rights in an item than s/he, by law, holds, but of course the custodian, upon coming into possession of items of a certain character (ie: excised tissue and associated transfer agreement), may have a wider range of interests and exercisable rights than that held by the conveying originator.

⁴⁷ It is well known that trust is an essential component of the success of biobanks and of medical research more generally: see M. Hannson, “Building on Relationships of Trust in Biobank Research” (2005) 31 JME 415-418, and G. Haddow, G. Laurie, S. Cunningham-Burley and K. Hunter, “Tackling

(2) Retention: Assuring Biobank Continuity

Obviously, if biobanks are to deliver their anticipated benefits, they need long life spans and an ever-growing (or at least large and relatively static) bio-resource inventory. As such, tissue/participant retention is essential. This is addressed in the proposed approach by the complete transfer of property interests from originator to custodian, which transfer is and should be explained to the originator as an exhaustion of the originator's rights; a severing of control over the originator's interests in relation to this particular material with the practical implication that individuals cannot withdraw their tissue/data from the biobank. It should, of course, be noted that the originator retains some influence through the participation in the general and specific public engagement exercises envisioned by the framework. Additionally, s/he might exercise influence by discontinuing the ongoing communication of health and other information, if that is part of the setup.

Currently, originator "consent" for the biobank to use his/her material can be withdrawn at any time and for any (and no stated) reason. Presumably, this right is included as a means of (1) preserving consent as a process, and (2) promoting public trust in the biobank. With respect to former, it must be conceded that this "process" falls well short of the ideal articulated above whereby consent involves an informational exchange undertaken within a relationship that facilitates that give-and-take – there is no true relationship here and information is often only obtained by the originator if s/he is prepared to educate herself.⁴⁸ With respect to public trust, it must be conceded that withdrawal misses the point utterly – if the originator is prepared to withdraw his/her consent, then, presumably, trust has already been lost and having (or exercising) a right to withdraw will do nothing to promote or rebuild that trust.

The right to withdraw (consent) is a curious entitlement in other respects as well. First, it is not clear what ongoing entitlement would underlie the exercise of the right:

- Property Right? Under current conceptions, the originator has no property in the material, so no foundation can be laid with respect to his/her ownership of the material, nor can any residual property rights in them be claimed.
- Integrity Right? Of course, once the tissue is excised, the originator is at no further risk of physical harm from any research to which it might be subjected, so the protection of one's own physical integrity cannot form its basis either.⁴⁹
- Privacy Right? The right to withdraw is not conditional on there actually arising a privacy concern, but if the originator feared injury from a breach of privacy point of view, there is no associated right to claim damages for a breach of the scope of consent given leading to privacy infringement.

Second, it is equally unclear what interests are being protected through the right. Having reference to those already identified, we can say the following:

Community Concerns About Commercialisation of Genetic Research: A Modest Interdisciplinary Proposal" (2007) 64 Social Science & Med 272-282.

⁴⁸ Although this may be as straight forward as consulting the biobank's website.

⁴⁹ It is difficult to imagine how the recognition of personality rights in continental systems would be infringed by the use of excised tissue and anonymised data in closed laboratory settings.

- It cannot be the interest of influencing use and disposal of excised tissue, for all one is doing by withdrawing is terminating use, not directing its use to ends considered to be more acceptable, and it fails to address the particular manner of disposal altogether.
- It cannot be the interest of influencing the profits that may be derived from the tissue, for individual withdrawals of tissue from the bank are unlikely to have any effect whatsoever on research agendas or formulations of benefit sharing.
- It cannot be the interest of freedom from emotional distress, for if one is withdrawing, then, again the distressful event has presumably already occurred to prompt the reaction (eg: the research project with which one has a problem has already been given access to the biobank or will proceed regardless of the presence of one's material).⁵⁰
- It might be the interest of autonomy, for one is exercising a choice, but withdrawing one's consent/material does not expand one's capability to influence research direction or facilitate one to participate in research deemed worthy (ie: it does not expand choice).
- It cannot be the interest of solidarity, for pulling out of (ethically approved) research does nothing to contribute to knowledge for the improvement of human well-being and health; indeed it weakens the resource base and makes practical outputs that much further away.

On the whole, then, the right of withdrawal, although preserving some minimal control over the material in the originator, is not a particularly effective right, and certainly not one that will seem satisfactory to the originator who still wishes to contribute to knowledge generation. Its primary effect is only to diminish the value of the biobank (and therefore the potential benefit to society). As such, as noted above, the transfer of control of the material to the custodian should be considered a final disposition by the originator. One need not recoil from this element of the model. First, it is familiar and accepted insofar as it is in keeping with how property interests can be (and are typically) divested. More importantly, it is only done in a setting with clear parameters for use, transparent processes for decision-making, and enforceable sanctions for failure to meet either. Most importantly, it preserves the biobank as a resource for good science and, ultimately, human healthcare improvement.⁵¹

⁵⁰ I concede that something short of an actual distress-provoking event may occur. For example, one's confidence in the system of protection may diminish, or one's view of privacy may simply change, but one imagines that, in the normal course, this will be a rarity.

⁵¹ I have tried to address the "what's in it for me" question, and it is the tragedy of our times or our nature that I am forced to do so. I concede that I may not have addressed it satisfactorily for those who feel I have taken something away (from the individual), but I suggest that, in exchange for that withdrawal, I have offered a strengthening of the overall system together with an assurance of (potentially) greater stability of the resource. Moreover, this is no less final than sample recruitment in the human stem cell setting where private or public/private entities secure material from which to derive stem cell lines.

CONCLUSION

One may charge that this criticism of the use of consent is a purely semantic (even pedantic) complaint, and consider it perfectly acceptable that “consent” can mean different things and demand different processes in different contexts within the medical setting. It may be that the complaint at the core of this article is indeed semantic, but language and terminology are important elements of creating and reaffirming social realities. The approach advanced here – its process and terminology – has the benefit of preserving the quality and strength of consent as it is used in the medical context, rather than stretching our understanding of it out of all proportion for the purpose of pursuing biobanks. Given the terrible atrocities that have been perpetrated against individuals in the name of medical research, the relatively recent and fragile break we’ve made with the heavily paternalistic practices of the past, and the fundamental link that consent (when approached robustly) has to realising certain moral values and human rights, this approach is both justified and reasonable.

One may question whether the practicalities of the approach outlined above are dramatically different from that which is already practiced in many cases. It may be that many elements of the model proposed are already contained in existing structures,⁵² but some of the most important elements – enforceable sanctions, user duties, and cessation of activities – are almost universally absent. This represents a more holistic regime which might be more likely to result in transplantation to other jurisdictions, thereby leading to greater harmonisation and more confident and effective use of research resources. Moreover, through the inclusion of oversight by a statutory authority with investigative and sanctioning powers, it goes further in protecting the interests of the public.

Finally, one may wonder at the exclusion in the model offered of an ability to withdraw, a circumscription of rights which (arguably) hints at a reversion to paternalism. It may be that complete divestment of control (other than participation in engagement exercises), with a concomitant inability to pull material out of the biobank, smacks of retrenchment and conflicts with the underlying concern for consent articulated. However, the biobank context is very different from the clinical and human subject research contexts, where a divestment of rights/interests could have very different consequences and, in any event, are permitted under certain conditions (eg: think of the proxy decision-maker situation). Further, as noted above, a right to withdraw is very different from, and in no way influences, research direction control. Withdrawal only diminishes the value of the resource contrary to its very *raison d’être* (which is to provide a broad-based resource with numbers capable of generating useful data in the genomic and systems biology era).

Let us be honest in the concession that, right or wrong, the body is currently seen (and largely treated) as an open source of biological material which can be mined for commercial gain by the elite alone – we are “biocows” to be “milked” (to borrow an image which arose at the Tiss:EU conference). Moreover, in the biobank context, we are (necessarily) treating people as means,⁵³ and we are trying to “clean” that instrumentalisation through some notional “consent” process, which is nothing like the consent that we usually demand in the medical context (and it does not deserve the

⁵² I take notice of the practices of UK Biobank, which has gone to great lengths to promote trust and transparency. For more on UK Biobank, see <http://www.ukbiobank.ac.uk/>.

⁵³ This is particularly so in instances where originators are not provided with information derived from their tissue that may be relevant to them, as is the norm.

title). As such, no one can agree on how to do it; the North American approach injects complexity and what might be unkindly characterised as a ruse;⁵⁴ the European approaches rely on differing ethical foundations and practicalities,⁵⁵ and they represent a shift from classical human subject research ethics without signalling that shift by offering a change of terminology.

If we wish to respect people, we should identify (and identify with) their interests and concerns, we should address their interests and concerns in the structures we rely on to steer our scientific endeavours (which are ever more powerful and influential on society), and we should be clear and transparent in the manufacture of the models we use to govern health science and the position of the individual in that endeavour. Focusing our efforts on imagining a principled and honest model that protects our achievements in related (medical) settings could facilitate the operation of biobanks. I have tried to do that here, drawing on a regime (ie: property) that individuals and communities can identify with, and one that is already insinuated in every aspect of the health research exercise.

This represents a preliminary exploration of a regime offering clarity around terms, practices and standards (re: sourcing, counselling, storing, coding and using samples) such that individuals might be assured that what they've agreed to will not be breached or exceeded, and that international collaborations can be pursued thereby maximising the benefits this valuable resource offers. I of course welcome further consideration or critical assessments of that preliminary exploration.

⁵⁴ See the terminological expansion articulated above and explained in footnote 19, *supra*.
⁵⁵ B. Elger & A. Caplan, *supra*, note 13, and B. Knoppers, *supra*, note 17.